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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,270	08/03/2001	Jurgen Kleinschmidt	8484-101-999	3472

7590 11/13/2003

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EXAMINER

WINKLER, ULRIKE

ART UNIT PAPER NUMBER

1648

DATE MAILED: 11/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

09/923,270

Applicant(s)

KLEINSCHMIDT ET AL.

Examiner

Ulrike Winkler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 13-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

The Amendment filed September 10, 2003 (Paper No. 13) in response to the Office Action of March 11, 2003 is acknowledged and has been entered. Claims 13-27 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

#### ***Drawings***

The office acknowledges the receipt of the formal drawing, the drawings have been approved by the Draftsperson.

#### ***Claim Rejections - 35 USC § 112***

The rejection of claims 13-27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of Applicant's amendments.

The rejection of claims 13-27 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention **is withdrawn** in view of Applicant's amendment.

#### ***Claim Rejections - 35 USC § 102***

The rejection of claims 13, 15, 17, 19, 20, 22, 24, 26 under 35 U.S.C. 102(e) as being anticipated by Colosi (U.S. Patent No. 6,004,797) **is withdrawn** in view of Applicant's amendment.

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The rejection of claims 5, 6, 8 and 9 (which should have been 13, 15, 17-19) under 35 U.S.C. 102(e) as being anticipated by Wang et al. (U.S. Patent No. 5,872,005) is **withdrawn** in view of Applicant's amendment.

New rejections in view of Applicant's amendment:

Claims 13-27 are objected to because of the following informalities: The claims use the abbreviation AAV, for clarity this should be spelled out the first time the abbreviation is used in the claims. Correction is required.

Claims 13-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to an "AAV helper virus sequence developing AAV viral particles" it is not clear from the claim construction that the AAV helper virus sequences are required for the production of AAV viral particles. Amending the claim to read "...adeno-associated helper virus sequences for developing adeno-associated viral particles" would help clarify the function of the claimed nucleic acid.

Claims 13 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Bett et al. (Proceeding of the National Academy of Science, 1994).

"Helper virus sequences" is defined (see page 2 line 28 to page 3 line 2) as herpes virus and/or adenoviruses sequences more preferably an adenovirus type 5 sequence. The sequences

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may comprise the entire adenovirus genome or a fragment of the genome. The claims read on an adenovirus with a deletion in of the E1 region.

Bett et al. discloses a sequence comprising the entire adenovirus type 5 with a deletion of the E1 region (see figure 4). Therefore, the instant invention is anticipated by Bett et al.

Claims 13, 17-20 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bett et al. (Proceeding of the National Academy of Science, 1994) and Colosi (U.S. Patent No. 6,004,797).

“Helper virus sequences” is defined (see page 2 line 28 to page 3 line2) as herpes virus and/or adenoviruses sequences more preferably an adenovirus type 5 sequence. The sequences may comprise the entire adenovirus genome or a fragment of the genome. The claims read on an adenovirus with a deletion in of the E1 region. The helper virus sequences are used to produce AAV viral particles.

Bett et al. teaches a sequence comprising the entire adenovirus type 5 with a deletion of the E1 region (see figure 4). The reference teaches growing the deleted virus in a 293 cell which has the adenovirus E1 genes inserted into the genome of the cell. The reference does not teach using the adenovirus as a helper virus for the production of AAV particles in a cell line.

Colosi teaches a method of producing AAV viral particles without using a helper virus (see column 5, lines 5-57). The non-AAV helper virus accessory functions, needed for AAV particle release, can be derived from adenovirus, herpesvirus and vaccinia virus (column 8, lines 29-39, column 17, lines 23-30; claim 10). Although the reference does not teach using an E1

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deleted adenovirus type 5, the reference does teach the necessary sequences that are required for the development of the recombinant AAV particles

It would have been obvious at the time the invention was made to use an E1 deleted adenovirus type 5 in a 293 cell to produce AAV particles. Although the focus of the Colosi reference is the production AAV particles using a vector encoding the minimal sequences necessary, there is nothing in the reference that would indicate the E1 deleted adenovirus in a 293 cell would not work for the purpose of producing an AAV particles. The E1 deleted adenovirus in a 293 cell comprises all the necessary sequences set out in Colosi to produce the recombinant AAV particles, indicating that the combination is suitable for the purpose of producing AAV particles. The selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Therefore, the instant invention is obvious over Bett et al. and Colosi.

### ***Conclusion***

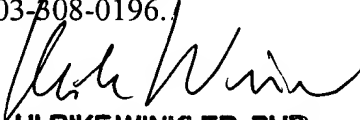
Claims 13-27 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
**ULRIKE WINKLER, PH.D.**  
**PATENT EXAMINER**

11/12/03